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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,291	12/08/2004	Masahiko Okada	262964US0XPCT	5683
22850 7590 07/13/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER WOOD, AMANDA P	
			ART UNIT 1657	PAPER NUMBER
			NOTIFICATION DATE 07/13/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.		Applicant(s)	
	10/516,291		OKADA ET AL.	
	Examiner		Art Unit	
	Amanda P. Wood		1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group IV, Claims 13-25 in the reply filed on 23 April 2007 is acknowledged. The traversal is on the ground(s) that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctiveness between the identified groups and that it has not been shown that a burden exists in searching the claims of the two groups. This is not found persuasive because the Examiner provided a specific example in the previous office action which indicated that the two inventions lacked a special technical feature that would relate to a single general inventive feature because the reagent used was known in the art at the time the claimed invention was made. Furthermore, in the previous office action, Applicant was clearly informed that should Applicant traverse the restriction based upon an argument that the inventions are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Applicant's arguments only consist of stating that the Examiner has not provided adequate reasons and/or examples to support a conclusion of patentable distinctiveness between the two inventions. However, based upon the lack of unity between the two groups in addition to the different search required of the two inventions (e.g., a search of the claimed reagent would not necessarily encompass a search of the claimed method steps), the restriction requirement set forth in the previous office action is still deemed proper and is therefore made FINAL.

The previous Office Action required restriction between product and process claims, but the Notice of Rejoinder was inadvertently left out of the previous office action. Please see the notice in its entirety below.

Claims 13-25 are presented for consideration on the merits.

Notice of Right to Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

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prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 recites the limitation "the lipoprotein lipase contained in the second reagent" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim with respect to the second reagent (see, e.g., claim 13, lines 11-14, wherein the second reagent merely comprises a selective reaction promoter capable of reacting with lipoprotein lipase, but there is no mention of lipoprotein lipase actually contained in the second reagent).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15, 19-21, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al (WO/0060112).

A reagent for selective measurement of triglycerides contained in very low density lipoprotein and intermediate density lipoprotein or in very low density lipoprotein in a test sample is claimed.

Okada et al teach a reagent comprising a reaction promoting agent (i.e., a selective reaction promoter) that can be a surface-active agent such as a polyoxyalkylene or a derivative thereof, including polyoxyethylene alkyl ether and polyoxyethylene alkyl phenyl ether (i.e., polyoxyalkylene straight-chain alkyl ethers). Okada et al teach that the reaction promoting agent reacts with lipoprotein lipase to eliminate triglycerides in lipoproteins other than very low density lipoproteins and intermediate density lipoproteins (i.e., VLDL and IDL) by carrying out a series of reactions which make hydrogen peroxide or reduced coenzyme. Okada et al teach that the enzymes used for decomposition of triglycerides into hydrogen peroxide for measurement include lipoprotein lipase, which gives glycerol, which is then changed to glycerol 3-phosphate by glycerol kinase, that changes into dihydroxyacetone-3-phosphate by glycerol-3-phosphate oxidase, followed by colored assay of the generated hydrogen peroxide. Also, Okada et al teach that glycerol-3-phosphate dehydrogenase can be used in lieu of glycerol-3-phosphate oxidase to produce NADH so that NADH can be measured (see, for example, Detailed Description section). Okada et al teach a first reagent comprising a reaction promoting agent and enzymes including lipoprotein lipase as well as other enzymes to produce either hydrogen peroxide or a reduced

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coenzyme, which eliminates the triglycerides from the lipoproteins other than the VLDL's and the IDL's, which includes those from LDL's and HDL's. Okada et al also teach a second reagent which then quantifies the triglycerides in the VLDL's and the IDL's, comprising a reaction promoting agent and enzymes which can react with the triglycerides to generate either hydrogen peroxide or a reduced coenzyme, wherein the reaction promoting agent can be a polyoxyalkylene or a derivative thereof, including polyoxyethylene alkyl ether and polyoxyethylene alkyl phenyl ether. Furthermore, Okada et al teach that the reagents may also contain reaction "auxiliary substances" (i.e., reaction assistants) which can assist the reaction promoter agents, examples of which include polyanion, halogen ion, and metal ions (see, for example, Detailed Description section).

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Okada et al in view of Matsui et al (US 6,194,164).

Okada et al is relied upon for the reasons set forth above.

Okada et al does not expressly teach a method wherein the average mole number of added polyoxyalkylene derivative is present in the first selective reaction promoter and the second reaction promoter in a particular ratio in relation to one another.

Matsui et al beneficially teach that preferred surfactants which act on lipoproteins other than LDL include polyoxyalkylene oxide derivatives having HLB (i.e., hydrophilic-lipophilic balance) values of not less than 13 and not more than 15. Matsui et al teach that one particular example is polyoxyethylene nonylphenyl ether (see, for example, col. 3, line 35). Matsui et al further teach that surfactants which act on all lipoproteins include polyoxyalkylene oxide derivatives having HLB values of not less than 11 and not more than 13, particularly polyoxyethylene nonylphenyl ether, for example (see, for example, col. 4, lines 10-40). Matsui et al beneficially teach that the method for calculating HLB of surfactants is well-known in the art, a method which is based in part upon the molecular weight of the hydrophilic portion of the surfactant (e.g., polyoxyethylene).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the reagent disclosed by Okada et al based upon the beneficial teachings provided by Matsui et al, with respect to the art-recognized method of using surfactants of a particular HLB value or molecular weight to solubilize specific lipoproteins, as discussed above. Okada et al specifically teach reagents which act on lipoproteins using surfactants that are derivatives of polyoxyalkylene and lipoprotein lipase so as to generate either hydrogen peroxide or reduced coenzyme to

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determine the amount of triglyceride in VLDL and IDL. Furthermore, Matsui et al particularly point out that polyoxyethylene nonylphenyl ether is one specific polyoxyalkylene derivative that is a preferred surfactant for acting on lipoproteins, and that the HLB value of a surfactant is important in determining its specificity toward lipoproteins. Matsui et al further beneficially teach that particular HLB values of surfactant are beneficial for acting on particular lipoproteins, and that calculating HLB values is well known in the art, and therefore, it would have been both obvious and beneficial for one of skill in the art at the time the claimed invention was made to use particular surfactants, as described by both Okada et al and Matsui et al, in particular mole number ratios of the polyoxyalkylene derivatives (i.e., the hydrophilic group) so as to vary the selectivity of the surfactant for different lipoproteins based upon the HLB value, as beneficially taught by Matsui et al. The result-effective adjustment of particular conventional working conditions (e.g., using a particular surfactant and/or using a particular ratio of added polyoxyalkylene in each of the selective reaction promoters) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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CHRISTOPHER R. TATE
PRIMARY EXAMINER